

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re Patent Application of:
Venkateswarlu Jasti et al.**

Application No.: 10/519,219

Confirmation No.: 7317

Filed: May 13, 2005

Art Unit: 1643

For: NOVEL TETRACYCLIC ARYLSULFONYL
INDOLES HAVING SEROTONIN
RECEPTOR AFFINITY USEFUL AS
THERAPEUTIC AGENTS, PROCESS FOR
THEIR PREPARATION AND
PHARMACEUTICAL COMPOSITIONS
CONTAINING THEM

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:
(Check one of the boxes A-D)

- ☐ A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above identified national application
- ☒ B. before the mailing date of a first office action on the merits, or a first office action after filing a request for continued examination.
- ☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary statement in box "i" below or paid the necessary fee in box "ii" below.

(check one of the boxes "i" and "ii" below:)

- ☐ i. Counsel states that, upon information and belief, each item of information listed herein was (check one of boxes (a) or (b))
- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.
- ☐ ii. Payment in the amount of the fee set forth in 1.17(p), presently believed to be \$180, is indicated below.
- ☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant petitions under 37 C.F.R. 1.97(d) for the consideration of this IDS. Under 37 CFR 1.17(i) a check in the amount of \$180.00 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was

(check one of the boxes "a" and "b" below:)

- ☐ (a) first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
- ☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A, B and/or C and fill in blanks, if appropriate.)

- ☒ A. Pursuant to the 37 C.F.R. § 1.98(a)(2)(ii), a copy/copies of the U.S. Patent(s) and/or U.S. Patent Application Publication(s) on PTO/SB08 is/are not being submitted.
- ☐ B. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.
- ☐ C. Certain documents were previously cited by or submitted to the Office in the following prior applications, which are relied upon under 35 U.S.C. 120:

<<INSERT SERIAL NO. & FILING DATE>>

Applicant identifies these documents by attaching hereto copies of the forms PTO-892, PTO-1449 and/or PTO/SB/08 from the files of the prior application(s) or a fresh PTO/SB/08 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application.

- ☐ 3. Cite No(s). _____ are not in the English language.
In accordance with 1.98(c), Applicant states:

- ☐ An English translation of each document (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.
- ☐ The requirement for a concise explanation of the relevance of any foreign language document is satisfied by the attached search report; citation of the documents cited in the search report shall not be construed as an admission that they are or are considered to be, material to patentability of the subject matter claimed herein (See MPEP §609).
- ☐ A concise explanation of the relevance of document(s) _____ is set forth as follows: [Insert concise explanation of relevance]
- ☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.
- ☐ A concise explanation of document(s) _____ can be found on the attached sheet.
- ☒ 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 in the preamble to the final rules; 1135 OG 13 at 20).
- ☒ 5. Other information being provided for the examiner's consideration follows:

An International Search Report, dated January 30, 2004, which issued during the international phase of International Application No. PCT/IN2003/000222, which corresponds to the present application.

6. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

Early and favorable consideration is earnestly solicited.

The Commissioner is authorized to charge any deficiency of up to \$300.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: April 12, 2007

Respectfully submitted,

By 

Adda C. Gogons

Registration No.: 29,714

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

Complete If Known

Application Number	10/519,219-Conf. #7317
Filing Date	May 13, 2005
First Named Inventor	Venkateswarlu Jasti
Art Unit	1643
Examiner Name	N. Grazier
Attorney Docket Number	03108/0202223-US0

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number/Kind Code ² (if known)			
AA	US-3,481,953		12/02/1969	Herbat	
AB	US-4,839,377		06/13/1989	Bays et al.	
AC	US-4,855,314		08/08/1989	Oxford et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ⁴ Number ⁵ /Kind Code ⁶ (if known)				
BA	WO 02/0788693		10/10/2002	Eli Lilly and Company		
BB	EP 0 457 701		02/22/1995	Immunotech S.A.		
BC	WO 94/06769		03/03/1994	Samjin Pharm. Co. Ltd.		
BD	WO 93/23396		11/25/1993	Merck Sharp & Dohme Ltd.		
BE	WO 93/00086		01/07/1993	Smith-Kline Beecham PLC		
BF	EP 0 497 512		08/05/1992	Merck Sharp & Dohme Ltd.		
BG	EP 0 438 230		07/24/1991	Merck Sharp & Dohme Ltd.		
BH	WO 91/18897		12/12/1991	The Wellcome Foundation Limited		
BI	EP 0 354 777		02/14/1990	Glaxo Group Limited		
BJ	EP 0 313 397		06/02/1993	The Wellcome Foundation Limited		
BK	EP 0 303 506		02/15/1989	Glaxo Group Limited		
BL	GB 2 035 310		06/18/1980	Glaxo Group Limited		
BM	WO 00/34242		06/15/2000	Virginia Commonwealth University		
BN	GB 2 341 549		03/22/2000	Merck Sharp & Dohme		
BO	JP-A 2000-026471		01/25/2000	Nippon Soda Co. Ltd.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication is appropriate. ¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ³
CA		Glennon, Richard A., et al. 2000. 2-Substituted Tryptamines: Agents with Selectivity for 5-HT ₂ Serotonin Receptors. <i>J. Med. Chem.</i> 43:1011-1018.	

Examiner Signature	Date Considered
--------------------	-----------------

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known Application Number 10/519,219-Conf. #7317 Filing Date May 13, 2005 First Named Inventor Venkateswarlu Jasti Art Unit 1643 Examiner Name N. Grazior Attorney Docket Number 03108/020223-USO	
Sheet	2	of	3	

CB	Tsai, Yuching, et al. 2000. N-(Banzanasulfonyl)tryptamines as Novel 5-HT ₆ Antagonists. <i>Bioorganic & Medicinal Chemistry Letters</i> 10:2295-2299.	
CC	Boess, Frank G., et al. 1998. The 5-Hydroxytryptamine ₂ Receptor-Selective radioligand [³ H]Ro 63-0653 Labels 5-Hydroxytryptamine Receptor Binding Sites in Rat and Porcine Striatum. <i>Molecular Pharmacology</i> 54:577-583.	
CD	Bourson, Anne, et al. 1998. Involvement of 5-HT ₂ receptors in nigro-striatal function in rodents. <i>British Journal of Pharmacology</i> 125:1562-1568.	
CE	Slaight, Andrew J. et al. 1998. Characterization of Ro 04-6790 and Ro 63-0563: potent and selective antagonists at human and rat 5-HT ₂ receptors. <i>British Journal of Pharmacology</i> 124:556-562.	
CF	Slaight, Andrew J., et al. The 5-hydroxytryptamine ₂ receptor: localisation and function. <i>Exp. Opin. Ther. Patents</i> 8(10):1217-1224.	
CG	Yoshioka, M., et al. 1998. Central Distribution and Function of 5-HT ₂ Receptor Subtype in the Rat Brain. <i>Life Sciences</i> 62(17/18):1473-1477.	
CH	Hoyer, Daniel, et al. 1994. VII. International Union of Pharmacology Classification of Receptors for 5-Hydroxytryptamine (Serotonin). <i>Pharmacological Reviews</i> 46(2):157-203.	
CI	Martin, G.R. and P.P.A. Humphrey. 1994. Receptors for 5-Hydroxytryptamine: Current Perspectives on Classification and Nomenclature. <i>Neuropharmacology</i> 33(3/4):261-273.	
CJ	Raess, Stephan, et al. 1994. Cloning and Characterisation of the human 5-HT _{5A} serotonin receptor. <i>FEBS Letters</i> 355(242-246).	
CK	Roth, Bryan L., et al. 1994. Binding of Typical and Atypical Antipsychotic Agents to 5-Hydroxytryptamine-6 and 5-Hydroxytryptamine-7 Receptors. <i>The Journal of Pharmacology and Experimental Therapeutics</i> 268(3):1403-1410.	
CL	Grossman, C.J., et al. 1993. Development of a radioligand binding assay for 5-HT ₂ receptors in guinea-pig and rat brain. <i>British Journal of Pharmacology</i> 109:818-824.	
CM	Monsma, Jr., Frederick J., et al. 1993. Cloning and Expression of a Novel Serotonin Receptor with High Affinity for Tricyclic Psychotropic Drugs. <i>Molecular Pharmacology</i> 43:320-327.	
CN	Rust, Martial, et al. 1993. A Novel Rat Serotonin (5-HT ₅) Receptor: Molecular Cloning, Localization and Stimulation of cAMP Accumulation. <i>Biochemical and Biophysical Research Communications</i> 193(1):268-278.	
CO	Schoeffter, Philippe, et al. 1993. SDZ 216-525, a selective and potent 5-HT _{1A} receptor antagonist. <i>European Journal of Pharmacology - Molecular Pharmacology Section</i> 244:251-257.	
CP	Shen, Yong, et al. 1993. Molecular Cloning and Expression of 5-Hydroxytryptamine ₂ Serotonin Receptor Subtype. <i>The Journal of Biological Chemistry</i> 268(24):18200-18204.	
CQ	Spadoni, Gilberto. 1993. 2-Substituted 5-Methoxy-N-acyltryptamines: Synthesis, Binding Affinity for the Melatonin Receptor, and Evaluation of the Biological Activity. <i>J. Med. Chem.</i> 36:4069-4074.	
CR	Glennon, Richard A. 1990. Serotonin Receptors: Clinical Implications. <i>Neuroscience & Biobehavioral Reviews</i> 14:35-47.	
CS	Lumma, Sarah C.R., et al. 1990. Characterization of 5-HT ₃ receptors in Intact N1E-115 neuroblastoma cells. <i>European Journal of Pharmacology - Molecular Pharmacology Section</i> 189:223-227.	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

Substitute for form 1449/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Application Number	10/519,219-Conf. #7317	
			Filing Date	May 13, 2005	
			First Named Inventor	Venkateswarlu Jasti	
			Art Unit	1643	
			Examiner Name	N. Grazier	
Sheet	3	of	3	Attorney Docket Number	03108/0202223-USO

CT	Saxena, Pramod R. and Carlos M. Villalón. 1990. Cardiovascular Effects of Serotonin Agonists and Antagonists. <i>Journal of Cardiovascular Pharmacology</i> 15(7):S17-S34.	
CU	Gershon, Michael D., et al. 1989. 5-Hydroxytryptamine and enteric neurones. In <i>The Peripheral Actions of 5-Hydroxytryptamine</i> . J. Fozard, editor. Oxford University Press, Oxford. 247-273	
CV	Schoeffler, Philippe and Daniel Hoyer. 1989. How selective is GR 43175? Interactions with functional 5-HT _{1A} , 5-HT _{1B} , 5-HT _{1C} and 5-HT _{1D} receptors. <i>Naunyn-Schmiedeberg's Arch. Pharmacol.</i> 340:135-138.	
CW	Waeber, C., et al. 1988. Molecular Pharmacology of 5-HT _{1D} recognition sites: Radioligand binding studies in human, pig and calf brain membranes. <i>Naunyn-Schmiedeberg's Arch. Pharmacol.</i> 337:595-601.	
CX	Hoyer, Daniel and Hans C. Neijt. 1988. Identification of Serotonin 5-HT ₂ Recognition Sites in Membranes of N1E-115 Neuroblastoma Cells by Radioligand Binding. <i>Molecular Pharmacology</i> 33:303-309.	
CY	Hoyer, Daniel, et al. 1985. Molecular Pharmacology of 5-HT ₁ and 5-HT ₂ Recognition Sites in Rat and Pig Brain Membranes: Radioligand Binding Studies with [³ H]5-HT, [³ H]8-OH-DPAT, (-)-[³ H]Iodocyanopindolol, [³ H]Mesulergine and [³ H]Ketanserin. <i>European Journal of Pharmacology</i> 118:13-23.	
CZ	Pazos, Angel, et al. 1985. The Binding of Serotonergic Ligands to the Porcine Choroid Plexus: Characterization of a New Type of Serotonin Recognition Site. <i>European Journal of Pharmacology</i> 106:539-546.	
CA1	Fuller, R.W. 1982. Drugs Acting on Serotonergic Neuronal Systems, in <i>Biology of Serotonergic Transmission</i> . Neville N. Osborn, ed. John Wiley & Sons. Chichester. 221-247.	
CB1	Leyson, J.E., et al. 1981. [³ H]Ketanserin (R 41 468), a Selective 3H-Ligand for Serotoning, Receptor Binding Sites. Binding Properties, Brain Distribution, and Functional Role. <i>Molecular Pharmacology</i> 21:301-314.	
CC1	Baldwin, J.E. ed. 1996. Reduction of Carbon-Carbon Bonds in Principles of Asymmetric Synthesis. 311-316.	
CD1	Tyers, M.B. 1991. 5-HT _{2A} receptors and the therapeutic potential of 5-HT ₂ receptor antagonists. <i>Therapie</i> . 46:431-436.	
CE1	Russell M.G. et al. 2001. N-Arylsulfonylindole derivatives as serotonin 5-HT _{2B} receptor ligands. <i>J. Med. Chem.</i> 44(23):3881-3895.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	Date Considered
--------------------	-----------------